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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/269,711	04/05/99	SAKAI	T 1/F3511PTUS

000513
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HM22/0828

EXAMINER	
WANG,S	
ART UNIT	**PAPER NUMBER**
1617	20

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/269,711	SAKAI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondenc address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. The request filed on June 7, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/269711 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 40-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method in vitro, (specification page 31), does not reasonably provide enablement for in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Particularly, the claims do not clearly specify the host to which the apoptosis inducing agent is administered. The claim or the specification does not provide sufficient guidance, direction or working examples. A skilled artisan would have been required to do undue experimentation to identify the host for said method.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 40-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 40 recites a method for inducing apoptosis comprising administering glycerolipid and/or glyceroglycolipid. The claim does not define the subject to which the glycerolipid and/or glyceroglycolipid is administered. The claims are indefinite as to what subject the glycerolipid and/or glyceroglycolipid is administered.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 40-43 and 45-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Winget (US Patent No. 5,620,962, of record).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget also teaches that purity of the glyceroglycolipid is important, i.e., the glyceroglycolipid should be free from other compounds, e.g., phospholipid. See column 1, lines 27-40, particularly, column 1, line 30. Winget further teaches a method for treating inflammation comprising administering the said composition to an animal in need. See column 2, lines 47-55. Winget does not expressly explain the detail biological functions of the glyceroglycolipid. Winget's method would inherent possess the apoptosis inducing process claimed herein. Applicants' attention is directed to *Ex*

parte Novitski, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

3. Claims 40 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazawa et al. (of record) or Nojima et al. (JP 60-19716, IDS, AA).

4. The references teach a method for treating cancers comprising administering glyceroglycolipid. See the abstract. The method would inherently possess the process of apoptosis inducing as discussed above.

Claims Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,620,962) and Yazawa et al. (IDS, AB), Nojima et al. (JP 60-19716, IDS, AA) in view of Nakai et al. (US Patent 5,672,603), and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993) for reason as discussed above.

Winget teaches a method for treating inflammation comprising administering glyceroglycolipid to an animal in need. See column 2, lines 47-55. Yazawa et al. and Nojima et al. teach a method for treating or preventing cancers comprising administering glyceroglycolipid. See the abstract. Winget further teaches the glyceroglycolipid See, may be obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget further teaches that glyceroglycolipid is present in many food products, e.g., lettuce, broccoli, wheat, etc. See column 1, 19-22.

The primary references do not teach expressly a method of inducing apoptosis. The primary references do not teach the employment of acid and/or base in the process of making the glyceroglycolipid.

However, Nakai et al. teaches that apoptosis is a physiological process which may occur under various physiological condition. See, column 1, lines 44-67. e.g., Apoptosis is involved in

cancer treatment when the cancer cells are killed. See column 2, lines 15-39. It is concluded that apoptosis regulating compounds or composition are useful as anticancer agent, antiretroviral agent, and therapeutical agent for autoimmune disease, for thrombocytopenia, for Alzheimer's disease and for various types of hepatitis, tumor metastasis inhibiting agent. See, column 4, lines 45-51. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glyceroglycolipid for inducing apoptosis.

A person of ordinary skill in the art would have been motivated to employ glyceroglycolipid for inducing apoptosis because glyceroglycolipids are known to be useful for treating or preventing cancer and apoptosis is known to be a part of physiological process of cancer treating. A person of ordinary skill in the art would reasonably expected that glyceroglycolipid would induce apoptosis since is a part of physiological process of cancer treatment. Furthermore, the employment of acid/base treatment in the process of making the glyceroglycolipid is seen to be obvious since the separation/purification of prior art glyceroglycolipids would be expected to increase the concentration of the active glyceroglycolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S. Wang

Shengjun Wang

AU 1617

August 23, 2001

RUSSELL TRAVERS
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